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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,112	04/17/2004	Reuben Matalon	P71641US0	9858

136 7590 10/15/2007

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
4133	

MAIL DATE	DELIVERY MODE
10/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,112	MATALON, REUBEN	
	Examiner	Art Unit	
	Meghan Finn	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 41-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-40* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/03/07; 8/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

On the Information Disclosure Statement received on August 16, 2004 has been considered. However citation #10 by Martyniuk et al. was not considered because there is no English or English abstract and citation #17 by Ahring et al. was not considered because it is lacking a required date of publication.

The amendment received on September 21, 2007 has been entered and applicant's response to the restriction requirement has also been entered. Applicant elected group II (claims 17-40) without traverse. Thus claims 17-40 will be examined.

Specification Objections

The disclosure is objected to because of the following informalities: The title is not descriptive. A suggested title is "Large Neutral Amino Acid Supplement for treatment of Phenylketonuria". Appropriate correction is required.

Claim Objections

Claim 17 is objected to because of the following informalities: Claim 17 claims a "LNAA" supplement but does not define "LNAA". Acronyms should be defined at least in the first claim in which they appear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Wachtel et al. (DE 40 37 447 A1).

In claim 17, applicant claims a large neutral amino acid (LNAA) supplement in which the weight ratio of the amino acids Leucine to Valine is greater than 2:1. Wachtel et al. teaches an amino acid composition consisting of Histidine, Isoleucine, Valine, Threonine, Methionine, Leucine, Tryptophan, Tyrosine, and Lysine (abstract) for the treatment of Phenylketonuria (PKU). They teach weight ratios which include a 2:1 ratio of Leucine to Valine (column 7, lines 46-60). The weight ratios of Wachtel et al. are % wt, but adjusted for a 500mg tablet the weights of each amino acid would be (±10% in brackets):

Lysine: 72.5 mg [22.5-122.5mg]

Histidine: 25 mg [0-75mg]

Isoleucine: 59.5mg [9.5-109.5mg]

Leucine: 101mg [51-151mg]

Methionine: 25.5 mg [0-74.5mg]

Threonine: 47.5mg [0-97.5mg]

Valine: 72mg [22-122mg]

Tryptophan: 18mg [0-68mg]

Tyrosine: 80mg [30-130mg]

Thus, since the ratio of leucine to valine can be as large as 151mg to 22mg which is a weight ratio of greater than 6:1 and thus Wachtel et al. anticipates claim 17.

Claim 19 claims a LNAA supplement comprising leucine and isoleucine in a weight ratio greater than 3:1. Wachtel et al. teaches in the composition shown above (column 7, lines 46-60) that the weight ratio of leucine to isoleucine can be as great as 15:1 (151mg leucine to 9.5mg isoleucine) and thus is significantly greater than 3:1. Thus Wachtel et al. anticipates claim 19.

Claim 20 merely recites combination of claims 17 and 19, and thus since both a 2:1 leucine to valine ratio and a 3:1 leucine to isoleucine ratio were taught as discussed supra, Wachtel et al. anticipates claim 20.

In claim 22, applicant claims a LNAA supplement with one or more LNAAs and specifically comprising lysine. Since the composition taught by Wachtel et al. (column 7, lines 46-60) contains lysine, Wachtel et al. anticipates claim 22.

Claims 23-31 are all claiming the LNAA supplement of claim 22, wherein the weight ratio of leucine to isoleucine is at least 3:1 and the weight ratio of leucine to

valine is at least 2:1. As discussed supra, Wachtel et al. teaches a composition (column 7, lines 46-60) that anticipates claims 23-31.

Claim 33 recites a LNAA supplement with specific weight ranges for several amino acids. As can be seen in the table 1 below, Wachtel et al. teaches a composition which has the same amino acids in the same range as that recited in claim 33. Thus claim 33 is anticipated by Wachtel et al.

Table 1: Comparison of supplement in claim 33 to that taught by Wachtel et al.

Amino Acid	LNAA of Claim 33 (mg in 500mg total)	Wachtel et al. (mg in 500 mg total)
Tyrosine	100-290	30-130
Tryptophan	25-75	0-68
Methionine	15-50	0-74.5
Isoleucine	15-55	9.5-109.5
Threonine	15-50	0-97.5
Valine	15-55	22-122
Leucine	15-200	51-151
Histidine	10-30	0-75
Lysine	5-200	22.5-122.5

Claims 34 and 35 further specify that the supplement of claim 33 contains between 10-30mg of lysine, and is substantially free of arginine. As can be seen in the composition taught by Wachtel et al. there is no arginine and the range of 10-30mg of

lysine is anticipated by Wachtel et al. and thus claims 34 and 35 are anticipated by Wachtel et al.

Claims 18, 21, 32, and 36 recite that the compositions of claims 17, 20, 22, and 33 are substantially free of phenylalanine. Wachtel et al. teaches their composition is free of phenylalanine (abstract), and furthermore it is not listed in the composition discussed above (column 7, lines 46-60). Thus Wachtel et al. teaches a composition free of phenylalanine and anticipates claims 18, 21, 32, and 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachtel et al. (DE 40 37 447 A1) in view of Ghadimi et al. (US 3,832,465, cited on applicant's IDS) in further view of Nakaki et al. (Beneficial Circulatory Effect of L-Arginine).

In claim 37, applicant claims a LNAA supplement that contains specific weights of amino acids per 600mg of total supplement. Table 2 compares the composition in claim 37 to the composition taught by Wachtel et al.

Table 2: Comparison of supplement in claim 37 to that of Wachtel et al.

Amino Acid	LNAA of Claim 37 (mg in 600mg total)	Wachtel et al. (mg in 600 mg total)
Tyrosine	100-290	36-156
Tryptophan	30-90	0-81.6
Methionine	25-75	0-89.4
Isoleucine	15-45	11.4-131.4
Threonine	15-50	0-117
Valine	15-50	26.4-146.4
Leucine	40-200	61.2-181.2
Histidine	15-45	0-90
Arginine	15-50	NONE

Wachtel et al. teaches a supplement that anticipates the ranges of each amino acid except arginine, which is not in the supplement of Wachtel et al.

Ghadimi et al. however, teaches a LNAA supplement and in table II (column 13, lines 24-44) Ghadimi et al. teaches a composition that contains arginine. Ghadimi et al. teaches 1000-2000mg per day wherein the total supplement is between 18750-53800mg. If you were to keep the same amino acid weight ratio for a 500mg total supplement the range would be between 26.6-53.3mg. It would have been obvious to one skilled in the art at the time of the invention to add arginine in the amount taught by Ghadimi et al. to the composition of Wachtel et al. because they are both amino acid compositions (containing leucine, isoleucine, tryptophan, tyrosine, methionine, lysine, valine, histidine, threonine). Furthermore, since treatment of PKU is started from infant stages and arginine is a necessary nutritional supplement for infants and growing children who cannot synthesize arginine fast enough to support growth requirements (Nakaki et al.), it would have been obvious to one skilled in the art at the time of the invention to add arginine for the production of a nutritional supplement that accommodates the dietary needs of infants afflicted with PKU and also eliminates the need to administer two separate amino acid supplements. Thus claim 37 is unpatentable over Wachtel et al. in view of Ghadimi et al. and Nakaki et al.

Claims 38-40 contain limitations clearly taught by Wachtel et al. as discussed above and thus since claims 38-40 are dependent on claim 37 they would be obvious

over Wachtel et al. in view of Ghadimi et al. and Nakaki et al. for the reasons discussed above.

Conclusion

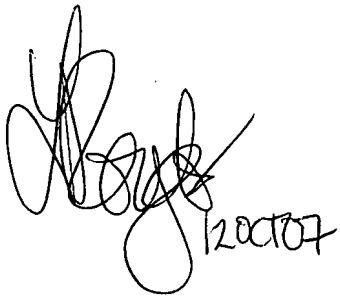
No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn



10/13/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER